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56. (new) The method of claim 54 further comprising the step of extracting the subject fluids via the aspiration element.
57. (new) The method of claim 54 further comprising the step of inserting an analysis element via the aspiration element.
58. (new) The method of claim 57 further comprising the substep of inserting the analysis element to a midpoint of the aspiration element.
59. (new) The method of claim 57 further comprising the substep of inserting to a distal end of the aspiration element.
60. (new) The method of claim 57 further comprising the substep of inserting the analysis element via the aspiration element into the site, the analysis element being disposed externally to the aspiration element.
61. (new) The method of claim 57 wherein the analysis element is a sensor.
62. (new) The method of claim 57 wherein the analysis element is a probe.

Remarks

Based on the above amendments, claims 10, 12-17, and 21-60 are currently pending. In the Office Action, the Examiner rejected claims 10 and 16 under 35 U.S.C. § 102(b) as being anticipated by Fischell. The Examiner further rejected claims 12-15, 17, 18, and 21-24 under 35 U.S.C. § 103(a) as being unpatentable over Fischell in view of Werp et al. Claim 18 has been deleted and new claims 25-60 have been added to more fully claim the present invention.

I. § 102(b) Rejections

Claims 10 and 16 were rejected under 35 U.S.C. § 102(b) as being anticipated by Fischell.

A. Independent Claim 10 Is Not Anticipated by Fischell

It is respectfully submitted that claim 10 is not anticipated by Fischell. Claim 10 is directed to a “device for detecting the concentration and/or existence of substances in body fluids.” Fischell, in contrast, discloses solely an injection device for subcutaneous delivery of medication. See Fischell, abstract, ll. 1-2 (emphasis added). For example, Fischell teaches that medication originating from an external pump passes through tubing and a flexible cannula and exits out an end hole of the cannula. See id., col. 6, ll. 48-54. Fischell does not teach the detection of concentration and/or existence of substances in body fluids. Thus, claim 10 is not anticipated by Fischell.

B. Independent Claim 16 Is Not Anticipated by Fischell

It is respectfully submitted that claim 16 is not anticipated by Fischell. Claim 16 requires “testing body fluids via said port member.” (emphasis added). Fischell, in contrast, teaches injection of medication by an injection device. See Fischell, abstract, ll. 1-2 (emphasis added). It does not teach testing of body fluids. In fact, the Examiner conceded that “Fischell does not teach the use of an access port for the testing of fluids in the body or originating within the body.” See Office Action of October 24, 2001, pg. 2, ll. 19-20. Thus, claim 16 is not anticipated by Fischell.

II. § 103 Rejections

Claims 12-15, 17, 18, and 21-24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Fischell in view of Werp et al. (“Werp”). Claim 18 has been deleted. It is respectfully submitted that claims 12-15, 17, and 21-24 are not made obvious by Fischell in view of Werp et al.

A. Dependent Claim 12 Is Not Made Obvious by Fischell in View of Werp Because the Cited References Do Not Disclose the Claimed Invention

It is respectfully submitted that claim 12 is not made obvious by Fischell in view of Werp.

The claimed invention in claim 12 is directed to a device that includes a tube arrangement through which a test sensor may be guided into the interior of the body. The tube arrangement extends “into the interior of the body.” See claim 12. Thus the device provides for a test sensor for use within the body or the device.

The arguments presented above are reiterated here and are incorporated herein by reference in the entirety. Fischell teaches injection of medication by an injection device. See Fischell, abstract, ll. 1-2. Fischell fails to teach or suggest testing of body fluids or the use of a test sensor.

Werp fails to remedy the deficiencies of Fischell. Werp teaches the use of an intercranial bolt as an access for taking biopsies and further teaches leaving the bolt in place pending testing of the biopsies. See Werp, col. 4, ll. 43-48. That is, the sample is removed from the body and tested externally to the body and the device. Werp fails to teach or suggest a test sensor or any other testing device for use within the intercranial bolt or the body. As a consequence, Werp fails to teach or suggest testing or the use of a test sensor within the body or device.

Neither reference, alone or in combination, teaches or suggests, provides any motivation or expectation of success to one having ordinary skill in the art that a test sensor could be inserted through a port device for testing of body fluids within the body or device. Therefore, one having ordinary skill in the art would find no motivation or expectation of success in the cited references, alone or in combination, to attempt to test body fluids via a porting device using a testing sensor for internal testing.

B. Claims 13 and 21-22, Depending from Claim 12, Are Patentable

Because claims 13 and 21-22 depend directly from claim 12 and incorporate all the limitations of claim 12, the above arguments obviate the basis for this ground of rejection. Thus, claims 13 and 21-22 are not made obvious by Fischell in view of Werp. Reconsideration and withdrawal of the rejection is respectfully requested.

C. Dependent Claim 14 Is Not Made Obvious by Fischell in View of Werp Because the Cited References Do Not Disclose the Claimed Invention

It is respectfully submitted that claim 14 is not made obvious by Fischell in view of Werp.

The claimed invention in claim 14 is directed to a device that includes a microdialysis probe by which substances in the body may be withdrawn.

The arguments presented above are reiterated here and are incorporated herein by reference in the entirety. Fischell teaches injection of medication by an injection device. See Fischell, abstract, ll. 1-2. Fischell fails to teach or suggest the withdrawal of substances nor the use of a probe for that withdrawal.

Werp fails to remedy the deficiencies of Fischell. Werp teaches the use of an intercranial bolt as an access for taking biopsies, insertion of a biopsy tool, and further teaches leaving the bolt in place pending testing of the biopsies. See Werp, col. 4, ll. 43-48. Werp fails to teach or suggest a microdialysis probe. As a consequence, Werp fails to teach or suggest the use of a microdialysis probe for withdrawal of a substance from the body.

Neither reference, alone or in combination, teaches or suggests, provides any motivation or expectation of success to one having ordinary skill in the art that a microdialysis probe could be used with a porting device for withdrawing substances from the body fluids. Therefore, one having ordinary skill in the art would find no motivation or expectation of success in the cited references, alone or in combination, to attempt to withdraw substances from body fluid via a porting device using a microdialysis probe.

D. Dependent Claim 15 Is Not Made Obvious by Fischell in View of Werp Because the Cited References Do Not Disclose the Claimed Invention

It is respectfully submitted that claim 15 is not made obvious by Fischell in view of Werp.

The claimed invention in claim 15 is directed to a port body having a shaft section with a disc-shaped anchoring section and a hollow enclosure containing an elastic self closing diaphragm, a feed tube, and an aspiration tube.

The arguments presented above are reiterated here and are incorporated herein by reference in the entirety. Fischell teaches injection of medication via an injection device with a single passage for administration of the medication. See Fischell, col. 6, ll. 48-54. Fischell fails to teach or suggest a device having two tubes extending into an interior region of the body and a catheter received in each tube.

Werp fails to remedy the deficiencies of Fischell. Werp teaches the use of an intercranial bolt providing access to the brain via a single bore and a single catheter capable of being inserted through the bore. See Werp, col. 4, ll. 4-5, 26-30. Werp fails to teach or suggest the use of two tubes with specific functions: a feed tube receiving a feed catheter and an aspiration tube receiving an aspiration catheter. As a consequence, Werp fails to teach or suggest the use of a feed tube and an aspiration tube receiving a feed catheter and an aspiration catheter, respectively.

Neither reference, alone or in combination, teaches or suggests, provides any motivation or expectation of success to one having ordinary skill in the art for the use of a port body having a hollow enclosure containing an elastic self closing diaphragm, a feed tube receiving a feed catheter, and an aspiration tube receiving an aspiration catheter. Therefore, one having ordinary skill in the art would find no motivation or expectation of success in the cited references, alone or in combination, to attempt to withdraw substances from body fluid via a porting device using a microdialysis probe.

E. Dependent Claim 17 and 23-24 Are Not Made Obvious by Fischell in View of Werp Because the Cited References Do Not Disclose the Claimed Invention

It is respectfully submitted that claims 17 and 23-24 are not made obvious by Fischell in view of Werp.

The claimed inventions in claims 17 and 23-24 are directed to a method of analyzing body fluids by testing the body fluids via a port member. See claim 16 (from which 17 and 23-24 depend). That is, the inventions require that the testing occur within the port member. Claim 17 further teaches the delivery of substances into the body. See claim 17. Claims 23 and 24 further disclose an anchor being implanted in or under the skin. See claim 23.

The arguments presented above are reiterated here and are incorporated herein by reference in the entirety. Fischell teaches only injection of medication by an injection device. See Fischell, abstract, ll. 1-2. Fischell fails to teach or suggest testing of body fluids.

Werp fails to remedy the deficiencies of Fischell. Werp teaches the use of an intercranial bolt as an access for taking biopsies and further teaches leaving the bolt in place pending testing of the biopsies. See Werp, col. 4, ll. 43-48. That is, the sample is removed from the body and tested externally to the body and the device. Werp fails to teach or suggest testing within the intercranial bolt. Werp, therefore, fails to teach or suggest testing via the disclosed device.

Neither reference, alone or in combination, teaches or suggests, provides any motivation or expectation of success to one having ordinary skill in the art for testing body fluids within the disclosed device. Claims 17 and 23-24, depending from claim 16, teach testing of body fluids via the porting member. Neither reference, alone or in combination, teaches or suggests testing within the disclosed device. Fischell teaches injection of medication by an injection device, and Werp teaches continual access via an intercranial bolt during external biopsy testing. The combination of these references fail to teach or suggest the claimed invention. Therefore, one having ordinary skill in the art would find no motivation or expectation of success in the cited references, alone or in combination, for testing body fluids via a porting member.

Conclusion

Applicant has obviated by argument the anticipation rejections of claims 10 and 16. Applicant has further obviated by argument the obviousness rejections of claims 12-15, 17, and 21-24. Applicant has deleted claim 18 and added new claims 27-62 to more fully claim the present invention.

This communication has added twenty-eight total number of claims, including two new independent claims, over those previously paid for. The office is hereby authorized to charge **Deposit Account No. 04-1420** in the amount of \$672.00, to cover the fee associated with the added claims. The Office is hereby authorized to charge any additional fees or credit any overpayment to **Deposit Account No. 04-1420**.

Reconsideration and a Notice of Allowance for all pending claims is respectfully requested.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Marked-up Version Showing Changes.**"

Respectfully submitted,

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MARKED-UP VERSION SHOWING CHANGES

In the Claims

18. (Deleted) [The method according to claim 17, wherein said port member provides for one of the partial or complete extraction of body fluids.]
27. (new) A device for subject fluid analysis, the device comprising:
- (a) an elastic self closing diaphragm;
 - (b) a feed element associated with the self closing diaphragm, the feed element being suitable for delivery of a substance into a subject; and
 - (c) an aspiration element associated with the self closing diaphragm, the aspiration element having a second distal end disposed opposite the elastic self closing diaphragm, wherein the aspiration element is suitable for accessing subject fluids.
28. (new) The device of claim 27 further comprising an analysis element insertably associated with the aspiration element, the analysis element being suitable for analysis of the subject fluids.
29. (new) The device of claim 28 wherein the analysis element is insertably disposed within the aspiration element.
30. (new) The device of claim 29 wherein the analysis element is insertably disposed at a midpoint of the aspiration element.
31. (new) The device of claim 28 wherein the analysis element is insertably disposed externally to the introduction element, the analysis element having been extended through the distal end of the aspiration element.
32. (new) The device of claim 28 wherein the analysis element is a sensor.

33. (new) The device of claim 28 wherein the analysis element is a probe.
34. (new) The device of claim 27 further comprising a feed tube disposable within the elastic self closing diaphragm and the feed element, the feed tube being suitable for delivery of the substance into the subject.
35. (new) The device of claim 34 wherein the feed tube is a catheter.
36. (new) The device of claim 27 further comprising an aspiration tube disposable within the elastic self closing diaphragm and the aspiration element, the aspiration tube being suitable for accessing the subject fluids.
37. (new) The device of claim 36 wherein the aspiration tube is a catheter.
38. (new) The device of claim 27 wherein the aspiration element is suitable for complete extraction of the subject fluids.
39. (new) The device of claim 27 wherein the aspiration element is suitable for partial extraction of the subject fluids.
40. (new) A method of analyzing subject fluids comprising the steps of:
- (a) accessing a site through an elastic self closing diaphragm associated with an introduction element;
 - (b) analyzing the subject fluids via a first tube disposable within the elastic self closing diaphragm and the introduction element.
41. (new) The method of claim 40 wherein the step of accessing a site further comprises the substep of implanting the elastic self closing diaphragm and the introduction element into the site.

42. (new) The method of claim 40 further comprising the step of delivering a substance into the site via the introduction element.
43. (new) The method of claim 42 wherein the substance is delivered via a second tube disposable within the elastic self closing diaphragm and the introduction element.
44. (new) The method of claim 42 further comprising the step of extracting the subject fluids via the introduction element.
45. (new) The method of claim 44 wherein the subject fluids are extracted via the first tube.
46. (new) The method of claim 40 further comprising the step of extracting the subject fluids via the introduction element.
47. (new) The method of claim 46 wherein the subject fluids are extracted via the first tube.
48. (new) The method of claim 40 further comprising the step of inserting an analysis element via the introduction element.
49. (new) The method of claim 48 further comprising the substep of inserting the analysis element to a midpoint of the introduction element.
50. (new) The method of claim 48 further comprising the substep of inserting the analysis element to a distal end of the introduction element.
51. (new) The method of claim 48 further comprising the substep of inserting the analysis element via the introduction element into the site, the analysis element being disposed externally to the introduction element.
52. (new) The method of claim 48 wherein the analysis element is a sensor.

53. (new) The method of claim 48 wherein the analysis element is a probe.
54. (new) A method of analyzing subject fluids and providing substances to the subject fluids comprising the steps of:
- (a) accessing a site through an elastic self closing diaphragm;
 - (b) delivering a substance to the site via a feed element associated with the elastic self closing diaphragm; and
 - (c) analyzing the subject fluids via an aspiration element associated with the elastic self closing diaphragm.
55. (new) The method of claim 54 wherein the step of accessing the site further comprises the substep of implanting the elastic self closing diaphragm into the site.
56. (new) The method of claim 54 further comprising the step of extracting the subject fluids via the aspiration element.
57. (new) The method of claim 54 further comprising the step of inserting an analysis element via the aspiration element.
58. (new) The method of claim 57 further comprising the substep of inserting the analysis element to a midpoint of the aspiration element.
59. (new) The method of claim 57 further comprising the substep of inserting to a distal end of the aspiration element.
60. (new) The method of claim 57 further comprising the substep of inserting the analysis element via the aspiration element into the site, the analysis element being disposed externally to the aspiration element.
61. (new) The method of claim 57 wherein the analysis element is a sensor.

62. (new) The method of claim 57 wherein the analysis element is a probe.